

IN THE CLAIMS:

Claims 4, 5, 29, 30, 52, 53, 72-79, 82, 83, and 106-113 were previously cancelled. Claims 1, 16, 20, 26, 49 and 62 have been amended herein. All of the pending claims are presented below. This listing of claims will replace all prior versions and listings of claims in the application. Please enter these claims as amended.

1. (Currently amended) An injectable depot composition for sustained delivery of a beneficial agent to a subject in a controlled manner over a predetermined duration of time after administration comprising:

(a) a viscous gel formulation comprising:

- (1) a bioerodible, biocompatible polymer, wherein the polymer is a blend of polymers including at least one lactic acid-based polymer and wherein the blend of polymers has a monomer ratio of at least 50% lactic acid-based polymer; and
- (2) a solvent having a miscibility in water of less than or equal to 7 wt.% at 25° C, in an amount effective to plasticize the polymer and form a gel ~~therewith;~~
therewith; and

(b) a beneficial agent dissolved or dispersed in the gel;

wherein the duration of time is from about two weeks to about twelve months after administration.

2. (Original) The composition of claim 1, wherein the polymer is a copolymer of lactic acid and glycolic acid.

3. (Original) The composition of claim 1, wherein the polymer is a polylactide.

4. (Cancelled)

5. (Cancelled)

6. (Original) The composition of claim 2, wherein the polymer has L/G ratio of about 50:50 to about 100:0 and a molecular weight ranging from about 3,000 to about 120,000.
7. (Previously presented) The composition of claim 1, comprising about 5 wt.% to about 90 wt.% of the bioerodible, biocompatible polymer.
8. (Previously presented) The composition of claim 7, comprising about 25 wt.% to about 80 wt.% of the bioerodible, biocompatible polymer.
9. (Previously presented) The composition of claim 7, comprising about 35 wt.% to about 75 wt.% of the bioerodible, biocompatible polymer.
10. (Previously presented) The composition of claim 1, wherein the duration of time is equal to or greater than three months after administration.
11. (Previously presented) The composition of claim 1, wherein the duration of time is from about 3 months to about 6 months after administration.
12. (Previously presented) The composition of claim 1, wherein the duration of time is from about 3 months to about 9 months after administration.
13. (Previously presented) The composition of claim 1, wherein the duration of time is from about 6 months to about 9 months after administration.

14. (Previously presented) The composition of claim 1, wherein the viscous gel further comprises a polymer selected from the group consisting of polylactides, polyglycolides, caprolactone-based polymers, poly(caprolactone), polyanhydrides, polyamines, polyesteramides, polyorthoesters, polydioxanones, polyacetals, polyketals, polycarbonates, polyphosphoesters, polyesters, polybutylene terephthalate, polyorthocarbonates, polyphosphazenes, succinates, poly(malic acid), poly(amino acids), polyvinylpyrrolidone, polyethylene glycol, polyhydroxycellulose, polysaccharides, chitin, chitosan, hyaluronic acid, and copolymers, terpolymers and mixtures thereof, and biodegradable polymers and their copolymers including caprolactone-based polymers, polycaprolactones and copolymers which include polybutylene terephthalate.

15. (Previously presented) The composition of claim 1, further including at least one of the following: a pore former; a solubility modulator for the beneficial agent; and an osmotic agent.

16. (Currently amended) The composition of ~~claim 1~~ claim 1, wherein the solvent comprises a component solvent selected from the group consisting of triacetin, diacetin, tributyrin, triethyl citrate, tributyl citrate, acetyl triethyl citrate, acetyl tributyl citrate, triethylglycerides, triethyl phosphate, diethyl phthalate, diethyl tartrate, mineral oil, polybutene, silicone fluid, glycerin, ethylene glycol, polyethylene glycol, octanol, ethyl lactate, propylene glycol, propylene carbonate, ethylene -carbonate, butyrolactone, ethylene oxide, propylene oxide, N-methyl-2-pyrrolidone, 2-pyrrolidone, glycerol formal, methyl acetate, ethyl acetate, methyl ethyl ketone, dimethylformamide, dimethyl sulfoxide, tetrahydrofuran, caprolactam, decylmethylsulfoxide, oleic acid, and 1-dodecylaza-cyclo-heptan-2-one, and mixtures thereof.

17. (Previously presented) The composition of claim 1, wherein the solvent is selected from an aromatic alcohol, lower alkyl and aralkyl esters of aryl acids; aryl, aralkyl and lower alkyl ketones; and lower alkyl esters of citric acid.

18. (Previously presented) The composition of claim 1, wherein the solvent is benzyl alcohol.
19. (Previously presented) The composition of claim 1, wherein the solvent is benzyl benzoate.
20. (Currently amended) The composition of ~~claim 1,~~ claim 1, wherein the solvent is ethyl benzoate.
21. (Original) The composition of claim 1, wherein the composition is free of solvents having a miscibility in water that is greater than 7 wt.% at 25° C.
22. (Previously presented) The composition of claim 1, wherein the delivery is a systemic delivery.
23. (Previously presented) The composition of claim 1, wherein the delivery is a local delivery.
24. (Previously presented) The composition of claim 1, wherein the delivery is repeated after a period of time.
25. (Previously presented) The composition of claim 1, wherein the delivery is provided at multiple sites.

26. (Currently amended) An injectable depot composition for sustained delivery of a beneficial agent to a subject in a controlled manner over a predetermined duration of time after administration comprising:

- (a) a viscous gel formulation comprising:
 - (1) a bioerodible, biocompatible polymer, wherein the polymer is a blend of polymers including at least one lactic acid-based polymer and wherein the blend of polymers has a monomer ratio of at least 50% lactic acid-based polymer; and
 - (2) a solvent having a miscibility in water of less than or equal to 7 wt.% at 25° C, in an amount effective to plasticize the polymer and form a gel therewith; and
- (b) a beneficial agent dissolved or dispersed in the gel;

wherein the beneficial agent is delivered systemically in a controlled manner over ~~the~~ a duration of time ~~the duration of time being~~ from about two weeks to about twelve months after administration.

27. (Original) The composition of claim 26, wherein the polymer is a copolymer of lactic acid and glycolic acid.

28. (Original) The composition of claim 26, wherein the polymer is a polylactide.

29. (Cancelled)

30. (Cancelled)

31. (Original) The composition of claim 27, wherein the polymer has L/G ratio of about 50:50 to about 100:0 and a molecular weight ranging from about 3,000 to about 120,000.

32. (Previously presented) The composition of claim 26, comprising about 5 wt.% to about 90 wt.% of the bioerodible, biocompatible polymer.

33. (Previously presented) The composition of claim 32, comprising about 25 wt.% to about 80 wt.% of the bioerodible, biocompatible polymer.

34. (Previously presented) The composition of claim 32, comprising about 35 wt.% to about 75 wt.% of the bioerodible, biocompatible polymer.

35. (Previously presented) The composition of claim 26, wherein the duration of time is equal to or greater than three months after administration.

36. (Previously presented) The composition of claim 26, wherein the duration of time is from about 3 months to about 6 months after administration.

37. (Previously presented) The composition of claim 26, wherein the duration of time is from about 3 months to about 9 months after administration.

38. (Previously presented) The composition of claim 26, wherein the duration of time is from about 6 months to about 9 months after administration.

39. (Original) The composition of claim 26, wherein the viscous gel further comprises a polymer selected from the group consisting of polylactides, polyglycolides, caprolactone-based polymers, poly(caprolactone), polyanhydrides, polyamines, polyesteramides, polyorthoesters, polydioxanones, polyacetals, polyketals, polycarbonates, polyphosphoesters, polyesters, polybutylene terephthalate, polyorthocarbonates, polyphosphazenes, succinates, poly(malic acid), poly(amino acids), polyvinylpyrrolidone, polyethylene glycol, polyhydroxycellulose, polysaccharides, chitin, chitosan, hyaluronic acid, and copolymers, terpolymers and mixtures thereof.

40. (Original) The composition of claim 26, further including at least one of the following: a pore former; a solubility modulator for the beneficial agent; and an osmotic agent.

41. (Previously presented) The composition of claim 26, wherein the solvent comprises a component solvent selected from the group consisting of triacetin, diacetin, tributyrin, triethyl citrate, tributyl citrate, acetyl triethyl citrate, acetyl tributyl citrate, triethylglycerides, triethyl phosphate, diethyl phthalate, diethyl tartrate, mineral oil, polybutene, silicone fluid, glycerin, ethylene glycol, polyethylene glycol, octanol, ethyl lactate, propylene glycol, propylene carbonate, ethylene carbonate, butyrolactone, ethylene oxide, propylene oxide, N-methyl-2-pyrrolidone, 2-pyrrolidone, glycerol formal, methyl acetate, ethyl acetate, methyl ethyl ketone, dimethylformamide, dimethyl sulfoxide, tetrahydrofuran, caprolactam, decylmethysulfoxide, oleic acid, and 1-dodecylazacyclo-heptan-2-one, and mixtures thereof.

42. (Original) The composition of claim 26, wherein the solvent is selected from an aromatic alcohol, lower alkyl and aralkyl esters of aryl acids; aryl, aralkyl and lower alkyl ketones; and lower alkyl esters of citric acid.

43. (Original) The composition of claim 26, wherein the solvent is benzyl alcohol.

44. (Original) The composition of claim 26, wherein the solvent is benzyl benzoate.

45. (Original) The composition of claim 26, wherein the solvent is ethyl benzoate.

46. (Original) The composition of claim 26, wherein the composition is free of solvents having a miscibility in water that is greater than 7 wt.% at 25° C.

47. (Previously presented) The composition of claim 26, wherein the delivery is repeated after a period of time.

48. (Previously presented) The composition of claim 26, wherein the delivery is provided at multiple sites.

49. (Currently amended) An injectable depot composition for sustained delivery of a beneficial agent to a subject in a controlled manner over a predetermined duration of time after administration comprising:

(a) a viscous gel formulation comprising:

- (1) a bioerodible, biocompatible polymer, wherein the polymer is a blend of polymers including at least one lactic acid-based polymer and wherein the blend of polymers has a monomer ratio of at least 50% lactic acid-based polymer; and
- (2) a solvent having a miscibility in water of less than or equal to 7 wt.% at 25° C, in an amount effective to plasticize the polymer and form a gel therewith; and

(b) a beneficial agent dissolved or dispersed in the gel;

wherein the beneficial agent is delivered locally in a controlled manner over a duration of ~~time~~ time from about two weeks to about twelve months after administration.

50. (Original) The composition of claim 49, wherein the polymer is a copolymer of lactic acid and glycolic acid.

51. (Original) The composition of claim 49, wherein the polymer is a polylactide.

52. (Cancelled)

53. (Cancelled)

54. (Original) The composition of claim 49, wherein the polymer has L/G ratio of about 50:50 to about 100:0 and a molecular weight ranging from about 3,000 to about 120,000.

55. (Previously presented) The composition of claim 49, comprising about 5 wt.% to about 90 wt.% of the bioerodible, biocompatible polymer.

56. (Previously presented) The composition of claim 55, comprising about 25 wt.% to about 80 wt.% of the bioerodible, biocompatible polymer.

57. (Previously presented) The composition of claim 56, comprising about 35 wt.% to about 75 wt.% of the bioerodible, biocompatible polymer.

58. (Previously presented) The composition of claim 49, wherein the duration of time is equal to or greater than three months after administration.

59. (Previously presented) The composition of claim 49, wherein the duration of time is from about 3 months to about 6 months after administration.

60. (Previously presented) The composition of claim 49, wherein the duration of time is from about 3 months to about 9 months after administration.

61. (Previously presented) The composition of claim 49, wherein the duration of time is from about 6 months to about 9 months after administration.

62. (Currently amended) The composition of ~~claim 49, wherein~~ claim 49, wherein the viscous gel further comprises a polymer selected from the group consisting of polylactides, polyglycolides, caprolactone-based polymers, poly(caprolactone), polyanhydrides, polyamines, polyesteramides, polyorthoesters, polydioxanones, polyacetals, polyketals, polycarbonates, polyphosphoesters, polyesters, polybutylene terephthalate, polyorthocarbonates, polyphosphazenes, succinates, poly(malic acid), poly(amino acids), polyvinylpyrrolidone, polyethylene glycol, polyhydroxycellulose, polysaccharides, chitin, chitosan, hyaluronic acid, and copolymers, terpolymers and mixtures thereof.

63. (Original) The composition of claim 49, further including at least one of the following: a pore former; a solubility modulator for the beneficial agent; and an osmotic agent.

64. (Previously presented) The composition of claim 49, wherein the solvent comprises a component solvent selected from the group consisting of triacetin, diacetin, tributyrin, triethyl citrate, tributyl citrate, acetyl triethyl citrate, acetyl tributyl citrate, triethylglycerides, triethyl phosphate, diethyl phthalate, diethyl tartrate, mineral oil, polybutene, silicone fluid, glycerin, ethylene glycol, polyethylene glycol, octanol, ethyl lactate, propylene glycol, propylene carbonate, ethylene carbonate, butyrolactone, ethylene oxide, propylene oxide, N-methyl-2-pyrrolidone, 2-pyrrolidone, glycerol formal, methyl acetate, ethyl acetate, methyl ethyl ketone, dimethylformamide, dimethyl sulfoxide, tetrahydrofuran, caprolactam, decylmethylsulfoxide, oleic acid, and 1-dodecylazacyclo-heptan-2-one, and mixtures thereof.

65. (Original) The composition of claim 49, wherein the solvent is selected from an aromatic alcohol, lower alkyl and aralkyl esters of aryl acids; aryl, aralkyl and lower alkyl ketones; and lower alkyl esters of citric acid.

66. (Original) The composition of claim 49, wherein the solvent is benzyl alcohol.

67. (Original) The composition of claim 49, wherein the solvent is benzyl benzoate.

68. (Original) The composition of claim 49, wherein the solvent is ethyl benzoate.

69. (Original) The composition of claim 49, wherein the composition is free of solvents having a miscibility in water that is greater than 7 wt.% at 25° C.

70. (Previously presented) The composition of claim 49, wherein the delivery is repeated after a period of time.

71. (Previously presented) The composition of claim 49, wherein the delivery is provided at multiple sites.

72.-79. (Cancelled)

80. (Previously presented) An injectable depot composition for sustained delivery of a beneficial agent to a subject in a controlled manner over a predetermined duration of time after administration comprising:

- (a) a viscous gel formulation comprising:
 - (1) a bioerodible, biocompatible blend of polymers, wherein the polymer is a blend of polymers including at least one lactic acid-based polymer and wherein the blend of polymers has a monomer ratio of at least 50% lactic acid-based polymer; and
 - (2) a solvent having a miscibility in water of less than or equal to 7 wt.% at 25° C, in an amount effective to plasticize the blend of the polymers and form a gel therewith; and
 - (b) a beneficial agent dissolved or dispersed in the gel;
- wherein the duration of time is from about two weeks to about twelve months after administration.

81. (Previously presented) The composition of claim 80, wherein the blend of the polymers includes a copolymer of lactic acid and glycolic acid.

82. (Cancelled)

83. (Cancelled)

84. (Previously presented) The composition of claim 80, wherein the blend of the polymers includes a polymer having an L/G ratio of about 50:50 to about 100:0 and a molecular weight ranging from about 3,000 to about 120,000.

85. (Previously presented) The composition of claim 80, comprising about 5 wt.% to about 90 wt.% of the bioerodible, biocompatible blend of the polymers.

86. (Previously presented) The composition of claim 85, comprising about 25 wt.% to about 80 wt.% of the bioerodible, biocompatible blend of the polymers.

87. (Previously presented) The composition of claim 85, comprising about 35 wt.% to about 75 wt.% of the bioerodible, biocompatible blend of the polymers.

88. (Previously presented) The composition of claim 80, wherein the duration of time is equal to or greater than three months after administration.

89. (Previously presented) The composition of claim 80, wherein the duration of time is from about 3 months to about 6 months after administration.

90. (Previously presented) The composition of claim 80, wherein the duration of time is from about 3 months to about 9 months after administration.

91. (Previously presented) The composition of claim 80, wherein the duration of time is from about 6 months to about 9 months after administration.

92. (Original) The composition of claim 80, wherein the viscous gel further comprises a polymer selected from the group consisting of polylactides, polyglycolides, caprolactone-based polymers, poly(caprolactone), polyanhydrides, polyamines, polyesteramides, polyorthoesters, polydioxanones, polyacetals, polyketals, polycarbonates, polyphosphoesters, polyesters, polybutylene terephthalate, polyorthocarbonates, polyphosphazenes, succinates, poly(malic acid), poly(amino acids), polyvinylpyrrolidone, polyethylene glycol, polyhydroxycellulose, polysaccharides, chitin, chitosan, hyaluronic acid, and copolymers, terpolymers and mixtures thereof.

93. (Original) The composition of claim 80, further including at least one of the following: a pore former; a solubility modulator for the beneficial agent; and an osmotic agent.

94. (Previously presented) The composition of claim 80, wherein the solvent comprises a component solvent selected from the group consisting of triacetin, diacetin, tributyrin, triethyl citrate, tributyl citrate, acetyl triethyl citrate, acetyl tributyl citrate, triethylglycerides, triethyl phosphate, diethyl phthalate, diethyl tartrate, mineral oil, polybutene, silicone fluid, glycerin, ethylene glycol, polyethylene glycol, octanol, ethyl lactate, propylene glycol, propylene carbonate, ethylene carbonate, butyrolactone, ethylene oxide, propylene oxide, N-methyl-2-pyrrolidone, 2-pyrrolidone, glycerol formal, methyl acetate, ethyl acetate, methyl ethyl ketone, dimethylformamide, dimethyl sulfoxide, tetrahydrofuran, caprolactam, decylmethylsulfoxide, oleic acid, and 1-dodecylazacyclo-heptan-2-one, and mixtures thereof.

95. (Original) The composition of claim 80, wherein the solvent is selected from an aromatic alcohol, lower alkyl and aralkyl esters of aryl acids; aryl, aralkyl and lower alkyl ketones; and lower alkyl esters of citric acid.

96. (Original) The composition of claim 80, wherein the solvent is benzyl alcohol.

97. (Original) The composition of claim 80, wherein the solvent is benzyl benzoate.

98. (Original) The composition of claim 80, wherein the solvent is ethyl benzoate.

99. (Original) The composition of claim 80, wherein the composition is free of solvents having a miscibility in water that is greater than 7 wt.% at 25° C.

100. (Previously presented) The composition of claim 80, wherein the delivery is a systemic delivery.

101. (Previously presented) The composition of claim 80, wherein the delivery is a local delivery.

102. (Previously presented) The composition of claim 80, wherein the delivery is repeated after a period of time.

103. (Previously presented) The composition of claim 80, wherein the delivery is provided at multiple sites.

104. (Previously presented) An injectable depot composition for sustained delivery of a beneficial agent to a subject in a controlled manner over a predetermined duration of time after administration comprising:

(a) a viscous gel formulation comprising:

- (1) a bioerodible, biocompatible blend of polymers, wherein the polymer is a blend of polymers including at least one lactic acid-based polymer and wherein the blend of polymers has a monomer ratio of at least 50% lactic acid-based polymer; and
- (2) a solvent having a miscibility in water of less than or equal to 7 wt.% at 25° C, in an amount effective to plasticize the blend of the polymers and form a gel therewith; and

(b) a beneficial agent dissolved or dispersed in the gel;

wherein the beneficial agent is delivered systemically in a controlled manner over a duration of time from about two weeks to about twelve months after administration.

105. (Previously presented) An injectable depot composition for sustained delivery of a beneficial agent to a subject in a controlled manner over a predetermined duration of time after administration comprising:

- (a) a viscous gel formulation comprising:
 - (1) a bioerodible, biocompatible blend of polymers, wherein the polymer is a blend of polymers including at least one lactic acid-based polymer and wherein the blend of polymers has a monomer ratio of at least 50% lactic acid-based polymer; and
 - (2) a solvent having a miscibility in water of less than or equal to 7 wt.% at 25° C, in an amount effective to plasticize the blend of the polymers and form a gel therewith; and
- (b) a beneficial agent dissolved or dispersed in the gel;

wherein the beneficial agent is delivered locally in a controlled manner over a duration of time from about two weeks to about twelve months after administration.

106.-113. (Cancelled)